



**CSP Research Priority Announcement Persian Gulf War Veterans' Illness Research**

**October 16, 1997**

**Office of Research and Development Letter**

**VA Cooperative Studies Program**

**Request for Applications - Persian Gulf War Veterans' Illnesses Research**

Purpose. The purpose of this Program Announcement is to solicit submission of Planning Request Letters for hypothesis-driven, multi-site, randomized clinical trials to study treatments proposed for Persian Gulf War Veterans Illnesses. Emphasis is placed on well-defined, clinically diagnosed subpopulations of Gulf War Veterans. Therapeutic approaches should emphasize therapies of demonstrated potential benefit and known risk. Planning Request submissions are open to all VA investigators but must be responsive to the content areas and parameters outlined in this announcement.

Background. In August of 1990, the United States began deployment of troops to the Persian Gulf area. Approximately 697,000 military personnel served in Saudi Arabia, Kuwait, Iraq and other countries in the Persian Gulf area. The fighting that took place from the middle of January 1991 until the cease fire on February 28, 1991 included 40 days of air warfare and five days of ground combat. While there were relatively few combat casualties and less than 200 battle deaths, Gulf War veterans were subject to a variety of environmental exposures, both natural and man-made, that could have potentially harmful effects on exposed individuals.

Within months of their return, a number of Gulf War veterans began to complain of a variety of symptoms many of which do not easily fit into well understood diagnostic categories. These symptoms include fatigue, musculoskeletal pain, and memory problems.

Content Areas. Listed below are Gulf War Illness research content areas appropriate for submission of a VA Cooperative Study Planning Request Letter.

- Treatment trials for disorders including chronic fatigue syndrome (CFS) and fibromyalgia (FM) patients who are Gulf War veterans, or other subgroups of Gulf War veterans with a clearly defined medical syndrome or diagnosis.
- Treatment trials of subgroups of Gulf War veterans with a clear diagnosis of post traumatic stress disorder (PTSD), somatoform disorder, or other psychiatric disorders.

- Candidate treatments for Phase II\* or Phase III\*\* randomized controlled trials of other defined subpopulations of Gulf War veterans for which proof of potential efficacy and safety have been demonstrated in either single or multi-site experimental trials.

\* Phase II trial (definition) - A trial involving a second stage of testing of a new treatment in human beings to generate preliminary information on efficacy and safety and associated side effects. The trial may be designed to include a control treatment and random assignment of patients to treatment.

\*\* Phase III trial (definition) - Any controlled trial among human beings using random assignment to a largely heretofore untested treatment measured against a control or another treatment intended primarily to generate information on efficacy.

#### Specifications.

- The study must address the therapy of individuals who meet published case criteria for the diagnosis of chronic fatigue syndrome, fibromyalgia, PTSD, or other conditions.
- At least 50% of the study population must be Gulf War veterans.
- The proposed therapy should be driven by a biologically plausible research hypothesis.
- "Established therapies" must be used; established therapies are those demonstrated to be effective and accepted as such in related or other patient populations. Interventions involving drugs or biologics should include only agents that are already licensed by the FDA for some therapeutic indication.

(Note - The definition of "established therapies" remains a point to be discussed and clarified among the Research Working Group on 10/16/97)

#### Application Process.

1. Interested investigators should contact Joe Gough, MA, Cooperative Studies Program Analyst to request a copy of [Instructions for Submission of a CSP Planning Request](#). CSP Planning Requests may be submitted at any time.
2. Submit five copies of the CSP Planning Request and curriculum vitae to: VA Headquarters, Cooperative Studies Program (124D), 810 Vermont Avenue, NW, Washington, DC 20420. All CSP Planning Requests will be reviewed by ad hoc experts in the field of research proposed. Notification of the Planning Request review disposition will be provided in approximately one month.
3. Investigators with an approved CSP Planning Request will be assigned by VA CSP Headquarters to one of the four VA Cooperative Studies Coordinating Centers for technical assistance and guidance in development of a full study protocol.

